Behind the scenes of screening for SVHCs

Subtitle

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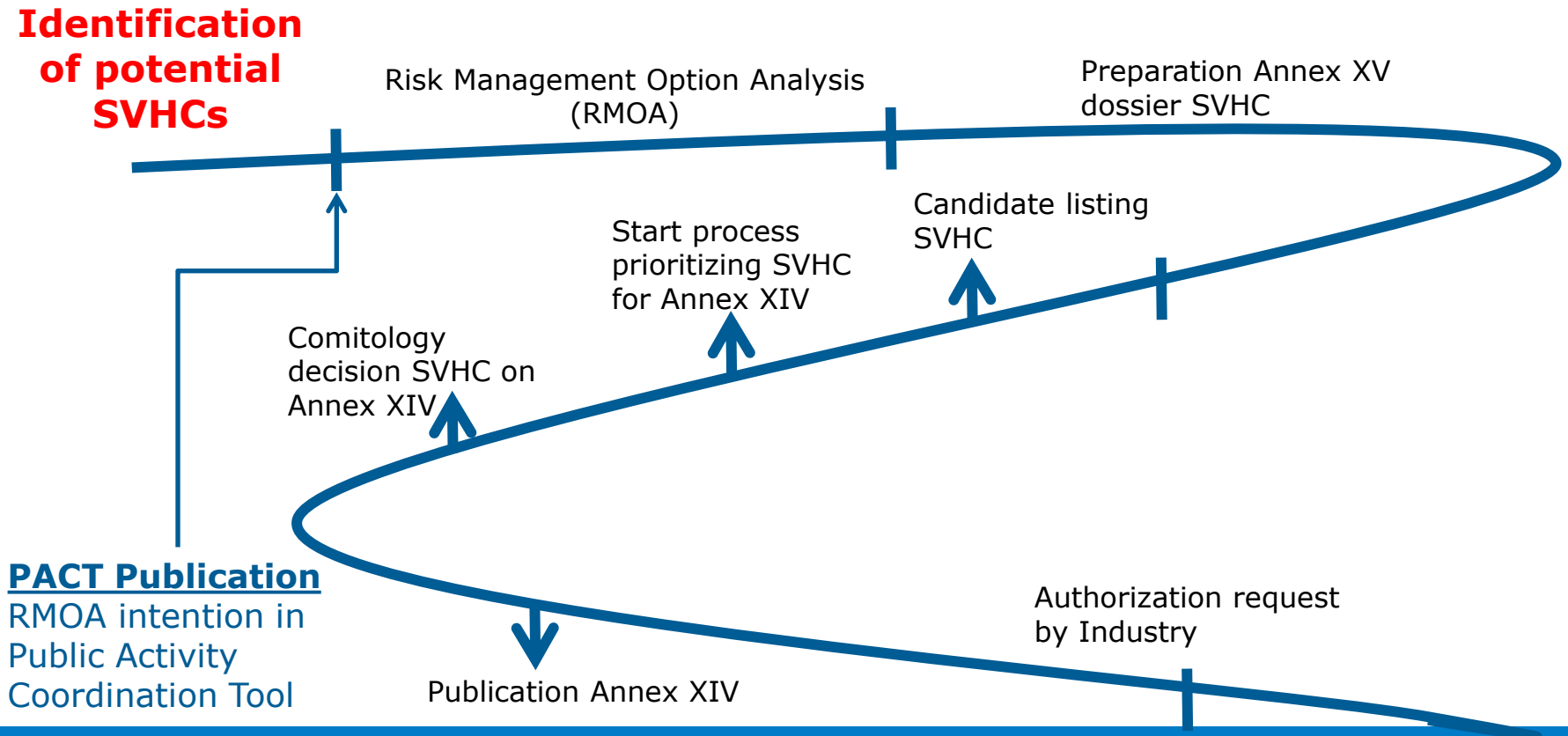
To refresh: the goal of the SVHC Roadmap

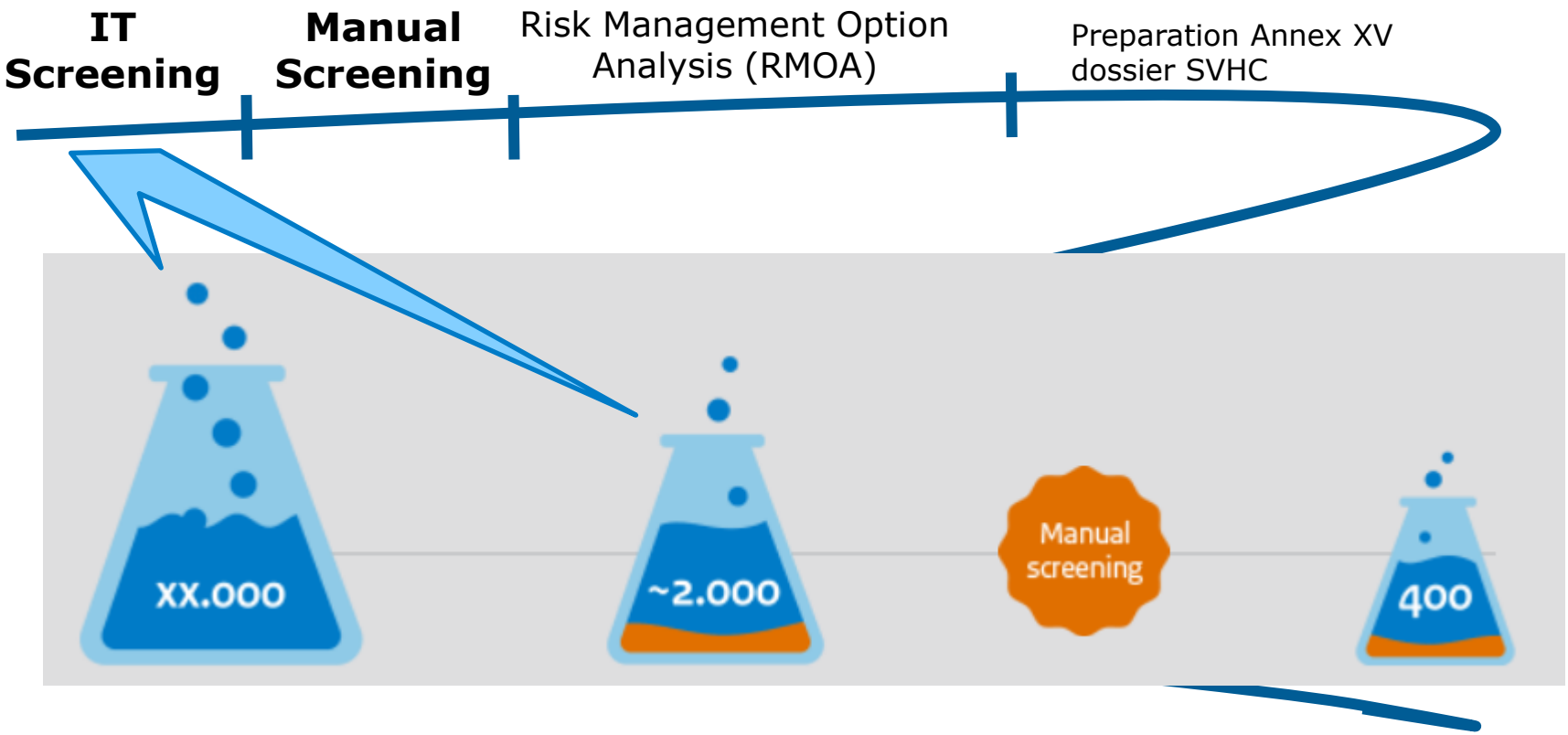
Assessment of all relevant substances of very high concern (SVHCs) in line with Art.57 of REACH by 2020 via a Risk Management Options Analysis (RMOA)

Increase transparency for Industry, Civil Society Organisations and the general public regarding the selection and assessment of SVHCs

From potential SVHC to SVHC – where are we?

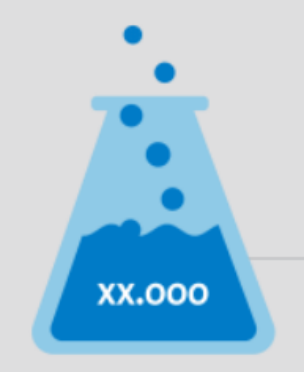


Screening for potential SVHCs



Hazard based selection – the Masterlist

1. Registered for **non-intermediate use** (art. 6; including impurities, constituents or additives) with:
   - harmonized classification CLP Cat.1 (CMR, Sens, STOT RE)
   - Self classification CLP Cat.1 (CMR, STOT RE)
   - Substances with an indication for:
     - Endocrine disruptive properties
       - (i.e. EC-, WHO-, SIN-list,…)
     - Persistency or bioaccumulative behaviour
       - (i.e. Log K_{ow}, BCF, T,…)
   - Non-classified but structurally similar to the above



2. Registered for **intermediate use** (art 17 and 18) or **non-registered** substances with a harmonized classification under CLP (see above) and that are at the same time structurally related to the above.

Exposure based prioritization – the Shortlist

- All substances from the Master list that may comply to the art 57 SVHC criteria based on their hazardous properties and that also score relatively high on:
  - produced tonnage
  - wide dispersive use
  - potential for environmental exposure
  - potential for human exposure

Joint exercise between ECHA and Member States to develop screening scenario's

Most important to realize

- ✓ The SVHC Roadmap aims at the identification of potential SVHCs
- ✓ Screening is primarily based on registration dossier (IUCLID)
- ✓ Hazard is the leading selection criterion for potential SVHCs
- ✓ Exposure related information is the leading prioritization criterion for potential SVHCs

It is essential that the registration dossier reflects the most recent toxicity information and actual uses

Time line of SVHC-prioritization

January
February
March
April
May
June
July
August
September
October
November
December

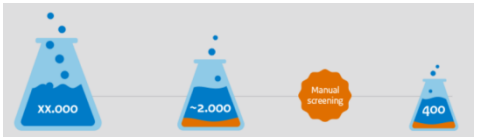
Substance Selection by Member States

Manual Screening by Member States

RMOAs

- Master list
- Short list

Evaluating and further development screening scenarios



From screening to SVHC – Conducting a RMOA

1. Select a substance of pot. concern
- SVHC Shortlist, other…

2. Perform a pre-assessment
Manual screening…
(IUCLID, CSR Pub-med…)

No Action, CCH, SEv

3. Start RMOA

- Contact IND for additional info

- Discuss and conclude on draft RMOA at Member State level

Discuss at RiME

4. Discuss draft RMOA with other MSCAs

5. Conclude RMOA

6. Conclusion on ACT
7. Non-conf. on PACT

Risk Management Expert Group (RiME)

Forum to discuss –most appropriate - risk management options for potential SVHCs

Participation: EU-Member States, the EU commission and ECHA

Main aim is:

- To give (non-binding and "off the record") advice
- To share knowledge and experiences related to risk management
- Exchange views on possible ways to best manage concerns/risks
- Where possible seek, common understanding or a harmonized approach
- When appropriate, initiate collaboration

Informal meeting

No fixed mandate or predefined scope

No official status, no minutes

What ECHA communicates on the SVHC Roadmap

Means of communication	Content
Website	SVHC Roadmap dedicated section on the ECHA website http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern
Description of screening approaches	Yearly update possible; http://www.echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-implementation-plan
Annual report on SVHC Roadmap implementation	1. Progress made on the implementation of the Roadmap 2. Planned activities for the upcoming year
Public Activities Coordination Tool (PACT)	Summarizing all substance specific activities: ongoing and follow-up; http://www.echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-implementation-plan/pact
Registry of Intentions (ROI)	Follow-up risk management actions (SVHC, Restriction, CLH); http://www.echa.europa.eu/web/guest/addressing-chemicals-of-concern/registry-of-intentions

To take home – Discussing Screening and RMOAs

- Authorities take the registration dossier (including the CSR) at face value;
- The registration dossier is the basis for Screening and RMOA. The information in there is the only one to be taken into account;
- Concern for hazard is leading for Screening and RMOA;
- Information on exposure is critical to prioritization in Screening and assess the most appropriate RMOA;
- When exposure data do not reflect reality substances may be selected for unjust reasons;
- When exposure data are too limited to identify specific risks:

  → Targeted restriction under REACH is no option;
- When Exposure data are too limited to exclude concerns:

  → RMOA based on reasonable worst case assumptions often leading to the authorization route as most appropriate regulatory option!

Thank You

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